

## SUPPLEMENT FACTS:

### Quatra 400mcg Chewable Tablets

Each chewable tablet contains:

Quatrefolic (M.S.).....400mcg

### Quatra 600mcg Chewable Tablets

Each chewable tablet contains:

Quatrefolic (M.S.).....600mcg

### 1st Generation - Food folate:

Refers to the various tetrahydrofolate derivatives naturally present in foods.

### 2nd Generation - Folic acid:

• It is a synthetic oxidized molecule that does not occur in nature but can be utilized by the human body as a precursor to form natural folates that are biologically active.

• Folic acid lacks coenzyme activity and must be reduced to the metabolically active form within the cell, through a series of biochemical steps before it can be used by the body's cells in vital metabolic pathways such as DNA production, cell reproduction and homocysteine metabolism.

### 3rd Generation (6s)-5-methyltetrahydrofolate calcium salt:

• The calcium salt of (6S)-5-methyltetrahydrofolate is available commercially and represents the third generation of folic acid. Until now, (6s) - 5 - methyltetrahydrofolate calcium salt was the only folic acid derivative available in the market, and able to penetrate the body cells without needing further metabolism.

### 4th Generation Quatrefolic, (6S)-5-methyltetrahydrofolate glucosamine salt:

• Quatrefolic is the glucosamine salt of (6S)-5-methyltetrahydrofolate and is structurally analogous to the reduced and active form of folic acid.

• Quatrefolic represents the fourth generation folate endowed with long lasting stability as well as a peculiarly high water solubility, improved bioavailability and well established safety.

**Chronology:** The generations of folate are:

1st generation folate (food)

2nd generation folate (synthetic folic acid)

3rd generation folate (reduced folate)

4th generation folate (Quatrefolic)

## CLINICAL PHARMACOLOGY:

### Mechanism of action

The mechanism of action of Quatrefolic is related to the action of 5-methyltetrahydrofolate the active part of the proprietary ingredient. 5-methyltetrahydrofolate derives from tetrahydrofolic acid, through a series of metabolic reactions. Tetrahydrofolic acid acts as a coenzyme in several vital metabolic reactions participating in the transfer as acceptors and donors of various one-carbon fragments, involved in the biosynthesis of nucleotides purines

and pyrimidines and in the metabolism of several important amino acids. In concern with vitamin B 12, folate coenzymes allow the conversion of the amino acid homocysteine to methionine, the lack of this conversion has been associated with various pathologies and diseases. Conversion of tetrahydrofolic acid to 5-methyltetrahydrofolate is mediated by the action of the enzyme methylenetetrahydrofolate reductase. Supplementation with 5-methyltetrahydrofolate might be preferable to folic acid, being it is immediately available to react with homocysteine to avoid the possibility of hyperhomocysteinemia.

### USAGE:

- During pregnancy and lactation
- Pregnant women for prevention of neural tube defect in babies
- As a dietary supplement in adults and older people
- To prevent risk of spontaneous abortions
- In hyperhomocysteinemia
- Folate deficiency caused by some medicines (e.g. those used to treat epilepsy such as phenytoin, phenobarbital and primidone)
- Folate deficiency caused by long-term red blood cell damage or kidney dialysis
- In Depression, Cognitive impairment, Dementia and Alzheimer's disease

### DOSAGE AND ADMINISTRATION:

- The intended uses of Quatrefolic and use levels will be same as that of folic acid, expressed on the basis of the "Recommended Dietary Allowances for Folate in Children and Adults"

AGE(years)	MALES & FEMALES (mcg/day)	PREGNANCY (mcg/day)	LACTATION (mcg/day)
-	Folate	-	-
1-3	150	-	-
4-8	200	-	-
9-13	300	-	-
14-18	400	600	500
19+	400	600	500

### CONTRAINDICATIONS:

- Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm has occurred from short courses of folate .Folic acid should never be given alone in the treatment of Addisonian, pernicious anemia and other vitamin B12 deficiency states because it may precipitate the onset of sub-acute combined degeneration of the spinal cord.
- Folic acid should not be used in malignant disease unless megaloblastic anemia owing to folate deficiency is an important complication. Known hypersensitivity to the active ingredient.

### WARNINGS AND PRECAUTIONS:

- Patients with vitamin B12 deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the sub-acute irreversible damage to the nervous system will continue. The deficiency can be due to undiagnosed megaloblastic anemia including in infancy, pernicious anemia or macrocytic anemia of unknown etiology or other cause of cobalamin deficiency, including lifelong vegetarians.
- Caution should be exercised when administering folic acid to patients who may have folate dependent tumours.



- This product is not intended for healthy pregnant women where lower doses are recommended, but for pregnant women with folic acid deficiency or women at risk for the reoccurrence of neural tube defects.
- Taking folic acid supplements might make seizures worse in people with seizure disorders, particularly in high doses.

**ADVERSE REACTIONS: Gastrointestinal disorders:** Anorexia, nausea, abdominal distension and flatulence.

Immune system disorders, Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnea, and anaphylactic reactions (including shock) .

**DRUG INTERACTIONS: Fosphenytoin:** Folic acid along with fosphenytoin might decrease the effectiveness of fosphenytoin for preventing seizures. **Methotrexate:** Folic acid along with methotrexate might decrease the effectiveness of methotrexate. **Phenobarbital:** Folic acid can decrease the phenobarbital effect for preventing seizures. **Phenytoin:** Folic acid along with phenytoin might decrease the effectiveness of phenytoin and increase the possibility of seizures. **Primidone:** Folic acid along with primidone might decrease how well primidone works for preventing seizures. **Pyrimethamine:** Folic acid might decrease the effectiveness of pyrimethamine for treating parasite infections. **Sulfasalazine:** Sulfasalazine can reduce the absorption of folic acid.

**USE IN SPECIAL POPULATIONS: Pregnancy:** US FDA Pregnancy Category A. Folic acid is likely safe when taken by mouth appropriately during pregnancy. Taking 600mcg of folic acid daily is commonly used during pregnancy to prevent birth defects and some neural Tube defects. **Nursing mothers:** Folic acid is actively excreted into human milk. No adverse effects in nursing infants have been associated with the use of folic acid during lactation.

**DOSAGE:** As directed by the physician.

**INSTRUCTIONS:** Store below 30°C. Protect from heat, sunlight & moisture. Keep out of the reach of children. This product is not intended for the diagnosis, treatment, cure or prevention of any disease.

**PRESENTATION:**

Quatra (Quatrefolic) chewable tablets 400mcg are available in Alu-Alu blister pack of 3x10's.  
Quatra (Quatrefolic) chewable tablets 600mcg are available in Alu-Alu blister pack of 3x10's.

**SHELF LIFE:** 2 Years.

خوراک: تفصیلی معلومات کیلئے ڈبے پر موجود کیو آر کوڈ اسکین کر کے مطالعہ کریں۔  
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔  
گرمی، سورج کی روشنی اور نمی سے محفوظ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔

Nutraceutical: Not for treatment of any disease  
نیوٹراسیوٹیکل: یہ پراڈکٹ کسی بیماری کے علاج کے لیے نہیں ہے۔

For detailed information:

**GENIX** Genix Pharma (Pvt.) Ltd.

44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.  
UAN: +92-21-111-10-10-11, Email: info@genixpharma.com



ISO 9001:2015



ISO 14001:2015



ISO 45001:2018

www.genixpharma.com